



October 26, 1999

Dear Mammography Medical Physicist:

The purpose of this letter is to announce the availability of a service that has been used previously by some members of your profession. Upon request, we have reviewed a medical physicist's credentials here at the headquarters of FDA's mammography program to determine whether or not the physicist meets the initial requirements under the final MQSA regulations. After the review, we send the physicist a letter with my signature identifying the initial requirements that he or she meets. The physicist can then provide this letter to the mammography facilities he or she serves. The information identified in this letter will be accepted by the MQSA inspector as adequate evidence that the cited initial requirements are met. Consequently, you will not need to provide your facilities with copies of the more detailed credentials that you sent to us for evaluation.

We understand that this service has been particularly valuable for medical physicists who serve many facilities because it reduces the amount of paperwork that they have to provide to each of their facilities. Physicists who are uncertain about whether or not they meet the initial requirements have also found this service useful for getting their questions related to the initial requirements answered.

We stress, however, that the decision to utilize this service is entirely yours. If you choose not to use this service, our inspectors will continue to evaluate your detailed credentials during their annual inspections of the mammography facilities you serve. Should you be interested in using this service, the enclosed "Questions and Answers" sheet contains additional details on the submission of your credentials that will be necessary for review.

Sincerely yours,

John L. McCrohan, M.S.
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Enclosure

QUESTIONS AND ANSWERS ON MEDICAL PHYSICIST REVIEW OF INITIAL REQUIREMENTS

1. Must I send the documentation of my credentials to the headquarters of FDA's mammography program for review?

No. While we are willing to provide this review as a service, whether you use the service is up to you. If you wish, you may continue to have all of your credentials reviewed during the annual inspection of the mammography facilities you serve.

2. What would be the advantage of sending my credentials to the FDA headquarters for review?

We see two possible benefits for you. First, if you are in doubt about whether you meet any of the initial requirements, this is an opportunity to get a definitive answer. Second, after the review a letter, signed by the Director of FDA's Division of Mammography Quality and Radiation Programs, will identify the initial requirements that you have met. This letter can be given to the facilities you serve in place of the documents related to those initial requirements that you presently provide to them for evaluation and credentialing purposes. This will reduce the volume of material that has to be given to the facility.

3. Will this review cover all of my MQSA personnel requirements?

No, it will be limited to the **initial requirements**. Your compliance with the continuing requirements will continue to be reviewed during the facility's annual MQSA inspection. Any requalification for these requirements also will be monitored by the inspectors and the FDA district offices. If you have a State approval or license that has to be renewed regularly, that credential will be reviewed during inspections and not at FDA headquarters.

4. What documents should I send to FDA headquarters for review?

Please refer to the table in the Medical Physicist section of our Guidance Document No. 2 for a detailed listing of appropriate documentation for the different requirements. You can find this documentation on our Web Site (www.fda.gov/cdrh/mammography) under "Guidance". Two questions in particular have been raised previously about this documentation. They are:

A. Must I provide a transcript or some similarly detailed document from my school to show that I have the required semester hours of physics or that my degree is in an acceptable field or both?

- If you send us a copy of your diploma and it clearly states that your degree is in physics or any of its specialties, such as medical or health physics, we will accept that as sufficient proof that (1) your degree is in an acceptable field and (2) you have the required hours of physics.
- If the copy of your diploma shows that your degree is in one of the other fields (chemistry, engineering, radiation science) accepted in the regulations, this will be sufficient proof that your degree is acceptable. However, we will also need a **transcript or other college document** to determine whether you have sufficient hours of physics.
- If the copy of your diploma does not indicate the field of your degree or indicates a field other than those identified in the regulations, we will need a transcript or other college document to determine whether (1) your degree can be considered to be in “physical science,” as defined in the regulations and (2) you have sufficient hours in physics.

B. Can I attest to any requirements?

- You can attest to contact hours of training in mammography surveys received and surveys performed before October 1, 1994. In addition, a sole owner of a physics consulting business can attest to surveys that he or she performed between October 1, 1994 and April 28, 1999. These attestations must be on a FDA-recommended form or one with the same elements. It must include as many details as you can remember.

NOTE: It is expected that if you can remember you did “x” number of surveys, you should also be able to remember the locations, although perhaps not the exact dates.

5. How long will it take FDA to perform this review?

We will perform a review as promptly as possible, but the actual time will depend on available staff time, the number of requests received, and the period of time in which we receive them. It will also depend on you. If your initial submission does not support a conclusion that you meet a particular requirement and you have to provide more material, this will obviously take more time.

6. What if one of my facilities is inspected while I am waiting to get my review back?

Until you receive the letter from us indicating that you have met the requirements **AND** you have provided a copy of the letter to the facility, our inspectors will determine whether you meet the initial requirements based on the documents you have provided to the facility.

7. What if this assessment of whether or not I meet the initial requirements disagrees with an earlier inspection finding?

In general, we do not plan on revisiting past inspection decisions. The letter you receive from us is intended for use during future inspections and will be accepted by MQSA inspectors.

8. How does FDA's letter relate to the State approval letter that I already have?

If you have a letter or other document from a State indicating that it has approved you for MQSA work, that letter will be sufficient proof that you meet the State approval option of the **requirement to be board-certified or State-licensed or State-approved**. It will not, however, address whether you meet the new initial requirements added in the final MQSA regulations. Only the letter from FDA (or if you choose not to participate in this review service, the inspector's evaluation during an inspection) can cover the new initial requirement.

9. Where do I send my credentials for review?

Mail them to the following address:

DHHS/PHS/FDA/CDRH
Office of Health and Industry Programs
Division of Mammography Quality and
Radiation Programs, HFZ-240
1350 Piccard Drive
Rockville, MD 20850
OR

You may fax the information to us at: 1-301-594-3306

In either case, mark them: ATTN: Kish Chakrabarti